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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,847	02/13/2002	Harry R. Howard JR.	PC11835A	9027
23913	7590	12/02/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			RAYMOND, RICHARD L.	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/075,847

Applicant(s)

HOWARD, HARRY R.

Examiner

Richard L. Raymond

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Change of Examiner***

1. Note the change of Examiner in the present application. The Art Unit number (1624) remains the same.

### ***Specification***

2. It is requested that a status paragraph be added as the first paragraph of the specification.
3. The two sheets of formulas (marked as drawings in e-DAN) are queried. Are these to be drawings or merely pages of the specification? Clarification is requested.

### ***Election/Restrictions***

4. In view of the original restriction requirement and as modified in the last Office action, claims 1 and 22-30 stand withdrawn from further consideration as being to a non-elected invention. Claims 2-21 are under consideration. For the record, method of use claims will be rejoined with the corresponding pharmaceutical composition claims upon allowance thereof.

***Response to Amendment***

5. The arguments in the Response of September 7, 2004 have been considered, but are not seen persuasive of error therein. They are repeated below along with an additional Section 112 rejection.

***Claim Rejections - 35 USC § 112***

6. Claims 2-21 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record. Applicants' arguments have been considered but are not seen persuasive of error therein.

7. Claims 2-18, 20 and 21 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (1) Claims 2-21 are incomplete in that they are dependent on non-elected claim 1. (2) Claims 21 is improperly dependent on itself. Apparently, dependency on claims 20 is intended. (2) Claims 2-18, 20 and 21 are indefinite in the definition of the second component of the composition merely as a GABA-A agonist. See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 where it was held that a chemical compound must be defined so as to distinguish it from other compounds. Merely defining it by its biological properties is insufficient.

***Claim Rejections - 35 USC § 103***

8. Claims 2-21 are again rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/37303 in view of WO 01/27068. Applicants' arguments have been considered but are not seen persuasive. It is maintained that these references together clearly teach the combination of SRI agents and GABA-A agonists, and for the present use. In the absence of a showing of unexpected properties, no patentable significance is seen in the present selection.


***Conclusion***

9. This action is **not** made final in view of the new grounds of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard L. Raymond whose telephone number is (571) 272-0673. The examiner can normally be reached on Monday-Thursday, 10:00 AM-8:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Richard L. Raymond  
Primary Examiner  
Art Unit 1624

rr  
November 27, 2004